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EXAMINER

HUI, SAN MING R

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MATHIAS C. ZOHOUNGBOGBO,
Appellant

Appeal 2008-005274
Application 09/982,554
Technology Center 1600

Decided: October 30, 2009

Before CAROL A. SPIEGEL, DONALD E. ADAMS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON REHEARING

Appellant requests a rehearing under 37 C.F.R. § 41.52(a)(1) of the Decision entered February 12, 2009 ("Decision") in which the obviousness rejections of claims 45-47, 49-52, and 54-56 were affirmed, but denominated as a new ground of rejection. We have jurisdiction under 35 U.S.C. § 134 (a).

I. Statement of the Case

The appealed claims are directed to a method of treating a person on a ketogenic diet to reduce the amount of cholesterol, triglycerides, glucose, uric acid, transaminases, and fibrinogen in the person's body by administering a defined composition. The composition administered in the method of claim 45 comprises (a) 7-23%¹ benfluorex or 14-17% ursodeoxycholic acid as a hypocholesterolemic agent, (b) 7-23% benfluorex as a hypotriglyceride agent, (c) 27-43% pancreatic IX F.U. as a lipasic and proteasic agent, (d) 36-41% metformin as a hypoglycemic agent, and (e) 9-14% Na dehydrocholate as a hydrocholeretic agent.

We agreed with the Examiner “that it would have been *prima facie* obvious to treat known side effects of a ketogenic diet, e.g., increased serum cholesterol, with a combination of known cholesterol-lowering drugs, e.g., benfluorex, metformin, and ursodeoxycholic acid” (Decision 10). However, we determined that the Examiner had not provided a sufficient factual basis to conclude “that it would have been *prima facie* obvious to incorporate pancreatin and sodium dehydrocholate into a cholesterol lowering composition containing metformin” (*id.*). Since the prior art disclosed an antispasmodic composition containing pancreatin and sodium dehydrocholate for treating abdominal cramps associated with flatulence (*id.* 6-7), we *sua sponte* found that the prior art disclosed that abdominal cramps (gastrointestinal pain) and flatulence (meteorism) are common side effects of taking metformin and, therefore, concluded “that it would have been *prima facie* obvious to include pancreatin and sodium dehydrocholate in a

¹ All references to “%” are to weight % of the total amount of the composition.

cholesterol lowering composition containing metformin” to treat the known common side effects of abdominal cramps and flatulence (*id.* 10-11). Thus, since our decision was based on a different factual basis than presented by the Examiner, it was designated as a new ground of rejection (*id.* 12).

We further noted that Appellant had not submitted evidence rebutting the Examiner's conclusion that optimizing the amount of each active agent in the composition would have been within ordinary skill in the art (*id.* 8 and 11) or other evidence of nonobviousness, such as evidence of unexpected results or synergy (*id.* 11).

II. Points Believed to have been Overlooked or Misapprehended

Appellant submits that "even if each of the references independently teach certain elements of the claims, there is no teaching or suggestion, nor is it implicit within the art, to combine the reference to arrive at the present invention" (RR² 4) absent hindsight reconstruction (*id.* 5). Appellant argues

[n]ot only were specific agents selected to treat specific side effects, but they were added within limited ranges. . . The ranges work, particularly in combination with the other components and the ranges claimed for them. Appellant acknowledges that for each component taken alone, there may be existing dosage knowledge, with routine experimentation needed to select one. However, the ranges claimed are for several claimed components and the requirement to show obviousness, must render obvious the relative concentrations to one another as that is what claim 45 is claiming, among other elements. [RR 6-7.]

Appellant also attached a copy of the April 16, 2003, Declaration of Mr. Zohoungbogbo to the Request for Rehearing (RR 1-2).

² Request for Rehearing filed 11 May 2009 ("RR").

III. Legal Principles

A request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board. Arguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing except that, upon a showing of good cause, Appellant may present a new argument based upon a recent relevant decision of either the Board or a Federal Court. 37 C.F.R. § 41.52(a)(1) and (2). New arguments responding to a new ground of rejection made pursuant to § 41.50(b) are permitted. 37 C.F.R. § 41.52(a)(3).

When the Board makes a new ground of rejection, the Appellant may ask for prosecution to be reopened before the Examiner. 37 C.F.R. § 41.50(b)(1).

IV. Analysis

Appellant essentially reiterates the hindsight reconstruction arguments made in the Brief. As stated in the Decision (Decision 8),

“The combination of familiar elements according to known methods is likely to be obvious when it does nothing more than yield predictable results.” *KSR*, 127 S.Ct. at 1739. “It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). “[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). *See also In re Reese*, 290 F.2d 839 (CCPA 1961).

Here, it would have been obvious to combine the known cholesterol lowering agents, benfluorex, metformin, and ursodeoxycholic acid into a single composition to treat known side effects of a ketogenic diet, such as elevated serum cholesterol. It would have been further obvious to add pancreatin and sodium dehydrocholate to the metformin-containing composition to relieve the known *common* side effects of metformin (Decision 8 and 10-11). It is well established that the Examiner's/Board's reason for incorporating pancreatin and sodium dehydrocholate into the metformin-containing composition need not be the same as Appellant's. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); *In re Dillon*, 919 F.2d 688, 693-94 (Fed. Cir. 1990). Since this argument has already been addressed in the Decision, it cannot have been overlooked or misapprehended.

Appellant newly argues that the prior art must not only suggest combining the claimed components into a composition, but also in their recited percentage weight (RR 6-7). However, Appellant has not shown good cause why this argument was not earlier presented in its Brief since it could have been made in response to the Examiner's conclusion that optimizing the amount of each active agent in the composition would have been within ordinary skill in the art. Nonetheless, we recognize that new arguments responding to a new ground of rejection made pursuant to § 41.50(b) are permitted. 37 C.F.R. § 41.52(a)(3). However, as noted in the Decision, Appellant has not submitted evidence showing that optimizing the amount of each active agent in the composition would have been outside the ordinary skill in the art (Decision 8 and 11) or other evidence of nonobviousness, such as evidence of unexpected results or synergy (*id.* 11).

In re Schulze, 346 F.2d 600, 602 (CCPA 1965) (argument in the brief does not take the place of evidence of record).

Finally, while the Zohoungbogbo Declaration attached to the Request for Rehearing was not attached to Brief, its substance was argued by Appellant in the Brief at page 17, i.e.,

the inventor Mr. Zohoungbogbo, stated that administration of the composition from Example 8 to patients undergoing a ketogenic diet ... maintained normal levels of cholesterol, triglycerides, glycemia, uric acid, transaminases and fibrinogen.

* * * * *

... on page 5, last paragraph, Mr. Zohoungbogbo further states ... "Nobody has demonstrated a surprising synergic effect of a composition as the one of my invention comprising more than two active ingredients."

As stated in the Decision, the composition of Example 8 is outside of the claimed subject matter because it contains 46.1% metformin (Decision 12). Since the showing in the Zohoungbogbo Declaration is not commensurate in scope with the claimed invention, it is insufficient to rebut the *prima facie* conclusion of obviousness.

V. Conclusion

Accordingly, we decline to reverse our decision of February 12, 2009 that claims 45-47, 49-52, and 54-56 are unpatentable as obvious under 35 U.S.C. § 103(a) over the applied prior art.

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VI. Order

Upon consideration of the record, and for the reasons given, it is
ORDERED that the request for rehearing is DENIED.

DENIED

rvb

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Application 09/982,554

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